both the above-identified patent application and in United States Patent No. 6,183,497. Withdrawal of this rejection is respectfully requested.

The 35 U.S.C. § 102 Rejection

Claim 7 stands rejected under 35 U.S.C. § 102(e) as being allegedly anticipated by Riley et al. or Chuang et al. This rejection is respectfully traversed.

According to the M.P.E.P., a claim is anticipated under 35 U.S.C. § 102(a), (b) and (e) only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.[1]

Claim 7 provides for "positioning a pledget of absorbable sponge material adjacent the vascular tissue site wherein the absorbable sponge material includes a contrasting agent." As stated in the Specification, the "contrasting agent [is] incorporated in the matrix of the sponge. By 'incorporated' is meant that the contrasting agent is substantially dispersed throughout the sponge so that the contrasting material is not simply found on the periphery of the sponge." (Specification, page 7, lines 26-29 and page 8, line 1). Thus, the contrasting material is substantially dispersed throughout the sponge such that the pledget already contains the contrast material prior to hydration and additional liquid contrasting agent is not required to be added.

claim 7 does not use this language

Riley and Chuang do not teach or suggest an "absorbable sponge material [which] includes a contrasting agent" as provided for in claim 1. Rather, Riley and Chuang teach the method of hydrating the Gelfoam with contrast medium or adding or injecting contrast medium separately from the Gelfoam. Specifically, Riley teaches filling the needle tract with opaque material and not the Gelfoam. (Riley, page 1, col. 2). Furthermore, Chuang teaches loading the Gelfoam into the tip of syringe, and then filling the syringe with contract medium from the back end thereby hydrating the Gelfoam with the contrast medium. (Chuang, page 1, col. 3, lines 3-7). Riley and Chuang both require the use of conventional, injectable liquid contrast medium since the Gelfoam itself does not contain any contrast medium and thus, do not teach the contrast medium substantially dispersed throughout the sponge material as required in claim 7.

Thus, it is respectfully requested that this rejection be withdrawn.

The 35 U.S.C. § 103 Rejection

Claims 8-11 and 14-27 stand rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Riley et al. or Chuang et al. in view of Daniels, US Patent No. 4,708,718, among which claims 16 and 22 are independent claims. This rejection is respectfully traversed.

According to the Manual of Patent Examining Procedure (M.P.E.P.),

[1] Manual of Patent Examining Procedure (MPEP) § 2131. See also *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

To establish a *prima facie* case of obviousness, three basic criteria must be met. First there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in the applicant's disclosure.[2]

Specifically, the Office Action contends:

"Both Riley et al. and Chuang et al. teach a method for performing a biopsy substantially as claimed. However, Riley et al. and Chuang et al. '718 do not explicitly state whether the agent is water soluble or insoluble and the type of materials thereof.

Daniels teaches in column 5, lines 41-62, a contrasting agent, wherein the agent may be water solute (i.e. iopamidol, matrizamide) or water insoluble (i.e. tantalum, barium sulfate).

Therefore, it would be have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Daniels, to construct a contrasting agent of either Riley et al. or Chuang et al. with the agent, as taught by Daniels, so that the agent can be made with either soluble material or insoluble material."

The Applicants respectfully disagree for the reasons set forth below.

Amended claim 16 provides for an "absorbable sponge material includes a contrast agent preloaded therein prior to hydration" and claim 22 provides for "an absorbable sponge material containing a contrast agent."

A. <u>There is no reasonable expectation of success.</u>

[2] M.P.E.P § 2143.

As stated above, the Specification provides that the "contrasting agent [is] incorporated in the matrix of the sponge. By 'incorporated' is meant that the contrasting agent is substantially dispersed throughout the sponge so that the contrasting material is not simply found on the periphery of the sponge." (Specification, page 7, lines 26-29 and page 8, line 1). Thus, the pledget already contains the contrasting material prior to hydration and additional liquid contrasting agent is not required and claimed in amended claim 16 and 22.

Neither Riley, Chuang, nor Daniels teach or suggest an "absorbable sponge material includes a contrasting agent" as provided for in claim 16 and 22. Rather, Riley, Chuang, and Daniels teach the method of adding or injecting liquid contrast medium separately from the Gelfoam or to hydrate the Gelfoam. For example, Daniels teaching that the "collagen material may be mixed . . . with a contrasting agent" and the contrasting agent is therefore not incorporated into the collagen material as required in claims 16 and 22. (Col. 5, lines 48-49). Thus, there is no reasonable expectation of success.

B. The prior art references when combined do not teach or suggest all the claim limitations

As stated above, neither Riley, Chuang, nor Daniels teach or suggest an "absorbable sponge material includes a contrasting agent" as provided for in claim 16 and 22. Rather, Riley, Chuang, and Daniels teach the method of adding or injecting liquid

contrast medium separately and/or to the Gelfoam. Thus, the prior art references do not teach or suggest all the claim limitations.

In view of the foregoing, it is respectfully asserted that the claims are now in condition for allowance. It is respectfully requested that this rejection be withdrawn.

Dependent Claims

The argument set forth above is equally applicable here. The base claims being allowable, the dependent claims must also be allowable.

In view of the foregoing, it is respectfully asserted that the claims are now in condition for allowance.

Request for Allowance

It is believed that this Amendment places the above-identified patent application into condition for allowance. Early favorable consideration of this Amendment is earnestly solicited.

If, in the opinion of the Examiner, an interview would expedite the prosecution of this application, the Examiner is invited to call the undersigned attorney at the number indicated below.

Respectfully submitted,
THELEN REID & PRIEST LLP

Dated: February 19, 2003

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Version With Markings To Show Changes Made

In The Claims

Claim 16 was amended as follows:

16. (Once Amended) The method for performing a biopsy comprising the steps of:

removing tissue from a vascular site; and

positioning a pledget of absorbable sponge material substantially at the vascular site wherein the absorbable sponge material includes a contrast agent preloaded therein prior to hydration [delivery].